EXHIBIT 5

Inspections, Compliance, Enforcement, and Criminal Investigations

Capt'n Chucky's Crab Cake Company, LLC 7/21/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
PHILADELPHIA DISTRICT
900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia. PA 19106
Telephone: 215-597-4390

WARNING LETTER
11-PHI-18

OVERNIGHT MAIL
RETURN RECEIPT REQUESTED

July 21, 2011

Nancy A. Wojciehowski, CEO
Capt'n Chucky's Crab Cake Company, LLC
5159 W Chester Pike
Newtown Square, PA 19073-1101

Dear Mrs. Wojciehowski:

The U.S. Food and Drug Administration (FDA) inspected your seafood processing facility, located at 5159 W Chester Pike, Newtown Square, PA on January 31, 2011 through February 10, 2011. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. 342(a)(4)]. Accordingly, your Smith Island Crab Cakes, Cold Formed Jumbo Crab Lump Crab Cakes (Premium Breaded Jumbo Lump Crab Cake), Cold Formed Jumbo Crab Cakes, Rock Hall Crab Cakes, Creamy Crab Cakes (Crab Critters Appetizers), Maryland Crab Soup, Imperial Breaded Jumbo Lump Crab Cake, Imperial Breaded Stuffed Shrimp, and Breaded Shrimp Cake products are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

Furthermore, our review of the labeling for your "Crab Critters" Appetizer product indicates that this product is adulterated within the meaning of section 402(c) of the Act [21 U.S.C § 342(c)] and misbranded within the meaning of sections 403(e), 403(i), 403(k), 403(q), 403(w) and 403(x) of the Act [21 U.S.C. §§ 343(e), 343(i), 343(k), 343(q), 343(w), and 343(x)].

You may find the Act, FDA regulations, the Fish and Fisheries Product Hazards & Controls Guidance: 4th Edition (the Hazard Guide) through links in FDA's home page at www.fda.gov[1].

Your significant violations were as follows:

Seafood HACCP

1. You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and you must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However your firm does not have a HACCP plan for your Imperial Crab Cake Shrimp Cake, and Stuffed Shrimp products to control the food safety hazards of pathogen growth, toxin formation, undeclared sulfites, and allergenic substances inclusion.

Please be advised that in accordance with 21 CFR 123.6(b)(2) your firm may group kinds of fish and fishery products together, or group kinds of production methods together if the food safety hazards, critical control points, critical limits, and procedures identified are identical for all fish and fishery products so grouped or for all production methods so grouped.

2. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b) and (c)(7). However, your firm did not record monitoring observations for your Creamy Crab Cakes, Smith Island Crab Cakes, Cold Formed Jumbo Lump Crab Cakes, and Maryland Crab Soup at various critical control points to control pathogen growth and toxin formation due to time or temperature abuse listed in your HACCP plan. For example, your firm had no monitoring records for temperature at the "Cooking Soup" critical control point as listed in your HACCP Plan for your Maryland Crab Soup. Further, our investigator observed that on January 31, 2011, during the manufacturing of this product, your cook failed to take any monitoring temperature of the product as required by your HACCP plan.

3. You must monitor sanitation conditions and practices during processing with sufficient frequency to ensure compliance with current good manufacturing practice requirements in 21 CFR Part 110, to comply with 21 CFR 123.11(b). However, your firm did not monitor: (1) the prevention of cross-contamination from insanitary objects to food from insanitary objects and (2) the condition and cleanliness of food contact surfaces with sufficient frequency to ensure compliance with the current good manufacturing practice requirements in 21 CFR Part 110 as follows:

A. On January 31, 2011, our investigator observed **(b)(4)** employees not wearing hair nets and working with food. Additionally, **(b)(4)** employees with mustaches had no hair restraints over their facial hair. These employees were observed emptying crab meat from cans into a plastic tote and each would smell the contents by placing their nose and moustache in close proximity to the crab meat prior to dumping each can. The bare-skin arm of one of these employees was in contact with the inside of the plastic tote during the process of dumping the crab meat into the tote. This cral meat was used in the production of Maryland Crab Soup on January 31, 2011;

B. On January 31, 2011, an employee was preparing onions for the manufacture of your Crab Critters Appetizers (Creamy Crab Cakes) on a butcher block type table surface, which was scored and had two holes extending through the block. These holes contained accumulated matter.

4. You must maintain sanitation control records that, at a minimum, document monitoring and corrections set out in 21 CFR 123.11 (b), to comply with 21 CFR 123.11 (c). However, your firm does not maintain any sanitation monitoring records. Under 21 CFR 123.11 (c), you are required to maintain, at a minimum, sanitation records that document the monitoring of the following conditions and corrections: (1) the safety of water that comes into contact wit food or food contact surfaces, or is used in the manufacture of ice; (2) condition and cleanliness of food contact surfaces; (3) prevention of cross-contamination from insanitary objects to food, food packaging materials, and other food contact surfaces, and from raw product to cooked product; (4) maintenance of hand washing, hand sanitizing, and toilet facilities; and (5) protection of food, food packaging material, and food contact surfaces from adulteration from chemical, physical, and biological contaminants.

5. You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (c) (1). A food safety hazard is defined in 21 CFR 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for your "Smith Island Crab Cake Battered &Breaded" product does not list the food safety hazard of Staphylococcus aureus growth and toxin formation. Your plan currently lists both "C. bot" and "Listeria," however hydrated batter and breading pose a risk specifically for Staphylococcus aureus growth and toxin formation.

6. You must have a HACCP plan that, at a minimum, lists monitoring procedures and their frequency for each critical control point, to comply with 21 CFR 123.6 (c)(4). However,

A. Your firm's HACCP plans for your "Smith Island Crab Cake Battered & Breaded", "Rock Hall Crab Cake", "Cold Formed Lump Crab Cakes", Cold Formed Jumbo Lump Crab Cakes" and "Creamy Crab Cakes" products list inadequate monitoring procedures at the "Receiving Pasteurized Crabmeat critical control point to control the identified hazards of "Bio" or "Biological C-bot" (i.e., toxin formation). Specifically, your monitoring procedures list that you will monitor the "Temperature" with a thermometer, however you do not state what will be monitored, i.e., whether you will be monitoring internal crabmeat container temperature, crabmeat container surface temperature, or temperature of the truck. Moreover, please be advised that taking a temperature at receipt, as currently listed in your plans, is only adequate when transit times are relatively short, for example less than 4 hours. When taking a temperature at receipt, we recommend that your firm assess or calculate the transit time to include all time outside a controlled temperature environment. In addition, we recommend that your plans include appropriate sampling strategies, such as taking temperatures of a minimum of 12 containers, unless there are fewer than 12 containers, in which case all of the container temperatures should be monitored;

B. Your firm's HACCP plans for "Smith Island Crab Cake Battered & Breaded", "Rock Hall Crab Cake", "Cold Formed Lump Crab Cakes" and "Cold Formed Jumbo Lump Crab Cakes" list inadequate monitoring procedures at the "Storing Crab Meat" critical control point to control identified hazards of "Bio C-bot" or "Biological C-bot" (i.e., toxin formation). Your plans list monitoring procedures that are the same as those listed for your receiving critical control point, in that a **(b)(4)** temperature is taken with a thermometer. However, there is no frequency listed, to indicate how often temperatures are taken and there is no indication of what will be monitored;

C. Your firm's HACCP plans for your "Creamy Crab Cakes" and "Cold Formed Lump Crab Cakes" products list an inadequate monitoring procedure at the "Defrosting of Vacuum Packages Pasteurized Surimi" and the "Defrosting of Modified Atmosphere Packaged Crab Meat" critical control points, respectively, to control the identified hazards of "Biological C-Bot" and "Biological C-Bot" (Le., toxin formation). Your plans list that you will monitor temperature **(b)(4)** for your "Cold Formed Lump Crab Cake" product, and that you will monitor each batch for your "Creamy Crab Cake" product. However, these procedures do not ensure that the frozen products are maintained at adequate temperatures for the entire duration of the thawing step to control pathogen growth and potential toxin formation (Le., as a biological hazard). We recommend that these products be defrosted or thawed in your refrigerators with the use of continuous monitoring and recording equipment to ensure that temperatures are continuously maintained at or below your listed temperature critical limits;

D. Your firm's HACCP plan for "Cold Formed Jumbo Lump Crab Cake" lists an inadequate monitoring procedure at the "Batter Mix Temp" critical control point to control the identified hazard of "Toxin Staph aureus." Specifically you do not list procedures that include what temperatures you intend to monitor; for example, that you will monitor the temperature of the hydrated batter mix and the time of exposure at the various corresponding temperature limits.

7. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However,

A. Your firm's HACCP plan for your "Cold Formed Jumbo Lump Crab Cake" product does not list adequate critical limits at the "Freezing Finished Product" critical control point to control "Bio C-Bot." Your plan states that you will keep the product **(b)(4)** and **(b)(4)** in a freezer within **(b)(4)** However, your critical limits do not ensure that the products are properly cooled to **(b)(4)** and then to **(b)(4)** within an additional **(b)(4)**

B. Your firm's HACCP plan for "Rock Hall Crab Cake" does not list any critical limits at the "Cooking/Blending Sauce" critical control point to control the listed hazard of "Biological C. Bot". Specifically, your plan does not include any cook times or temperatures. In addition there is no information provided regarding other cooking parameters that could affect the cook process (e.g. batch size/volume, ingredients);

C. Your firm's HACCP plan for your "Maryland Crab Soup" product:

- Does not list a critical limit for time at the "Cooking Soup" critical control point to control the identified hazard of "Bio C-Bot." In addition there is no information provided regarding other cooking parameters that could affect the cook process (e.g. batch size/volume, ingredients)..

• Lists a critical limit at the "Chill before Freezing" critical control point that is not adequate to control "Bio C-Bot." Specifically, your listed critical limits of **(b)(4)** to **(b)(4)** in **(b)(4)** Put in **(b)(4)** is not adequate because you do not list cooling the finished product to **(b)(4)** or below within an additional **(b)(4)**

8. Because you chose to include a corrective action plan in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan overall, do not list how you will correct the cause of the deviations. In addition, several of your corrective action plans do not appear to prevent distribution of potentially unsafe products. When amending your HACCP plans, you should ensure that your corrective actions accomplish both correcting the cause of the deviations and preventing potentially adulterated products from entering into commerce.

Labeling Violations

9. Your "Crab Critters" Appetizer product is misbranded within the meaning of Section 403(w) of the Act [21 U.S.C. 343(w)] in that the label for this product fails to declare the presence of major food allergens, as required by Section 403(w)(1) of the Act. Specifically you informed our investigator that this product contains the ingredient **(b)(4)** The label for the **(b)(4)** that your firm uses in the manufacture of your "Crab Critters" Appetizers product declares **(b)(4)** and **(b)(4)** as ingredients. However, the label for your "Crab Critters" Appetizer product does not declare the presence of **(b)(4)** In addition, your product bears the statement "Contains: crab, wheat, milk, soy ...." but this statement fails to include the food source of all major food allergens present in the product (e.g **(b)(4)**

Section 201 (qq) of the Act [21 U.S.C. 321 (qq)] defines as "major food allergens" milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with certain exceptions, e.g., highly refined oils derived from a major food allergen. A food is misbranded under Section 403(w) of the Act if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

i) The word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients [section 403(w)(1)(A) of the Act (21 U.S.C. 343(w)(1)(A))], or

ii) The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, (e.g. "flour (wheat)"), except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen [section 403(w)(1)(8) of the Act (21 U.S.C. 343(w)(1)(8))].

10. Your "Crab Critters" Appetizer product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. 343(i)(2)) in that this product is fabricated from two or more ingredients, but the label fails to bear the common or usual name of each ingredient, as required by 21 CFR 101.4 b. Specifically your "Crab Critters" Appetizers product contain **(b)(4)** mustard, and bread crumbs, which are multi-ingredient foods. However, the label for your "Crab Critters" Appetizers product does not declare the presence of the sub-ingredients in these multi-component foods in accordance with 21 CFR 101.4(b)(2).

The requirement to list component ingredients (or "sub-ingredients") may be met by either parenthetically listing the component ingredients after the common or usual name of the multi-component ingredient, or by listing the component ingredients without listing the multi-component ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the multi-component ingredient; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food [21 CFR 101.4(b)(2)).

11.Your "Crab Critters" Appetizer product is misbranded within the meaning of section 403(e)(2) of the Act [21 U.S.C. 343(e)(2)) in that the label for this product does not bear the net quantity of contents in accordance with 21 CFR 101.105. When the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, the declaration must be combined with a statement of weight, measure, or size of the individual units of the food as will provide such information [21 CFR 101.105(c)]. The product label for your "Crab Critters" Appetizers states "50 appetizers." This does not adequately describe the amount of food in the package because the weight, measure, or size of the individual appetizers can vary greatly.

12.Your "Crab Critters" Appetizer product is misbranded within the meaning of section 403(q)(1) of the Act [21 USC 343(q)(1)] because the label fails to bear nutrition information, as required by 21 CFR 101.9.

To determine whether your firm is eligible for an exemption from certain nutrition labeling requirements, you can review nutrition labeling exemptions at 21 CFR 101.90). In addition, for information on nutrition labeling exemptions for small businesses, you can review the FDA webpage at:
http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/[2]

SmallBusinessNutritionLabelingExemption/default.htm[3].

13.Your "Crab Critters" Appetizer product is misbranded within the meaning of section 403(k) [21 U.S.C. 343(k)] in that the product bears or contains artificial flavors, but the label fails to state that fact. As noted above our "Crab Critters" Appetizer product contains as an ingredient, **(b)(4)** The label for the **(b)(4)** that your firm uses in the manufacture of your "Crab Critters" Appetizer declares "artificial flavors" as an ingredient. However, the label for your "Crab Critters" Appetizer product fails to declare the presence of artificial flavors, as required by section 403(k) of the Act. The label of a food to which a flavor is added must declare the flavor in the statement of ingredients in accordance with 21 CFR 101.22(h).

14.Your "Crab Critters" Appetizer product is misbranded within the meaning of section 403(x) of the Act [21 U.S.C. 343(x)] in that this product contains a coloring that bears or contains a food allergen (other than a major food allergen) that is not disclosed in accordance with 21 CFR 73.100(d). Specifically your "Crab Critters" Appetizer product contains as an ingredient **(b)(4)** The label for the **(b)(4)** "carmine" as an ingredient. Carmine is a color additive that is an allergen for a subset of the allergic population. See 74 Fed. Reg. 207-01 (Jan. 5, 2009). Under 21 CFR 73.100(d)(2), the label of food products intended for human use that contain carmine must specifically declare the presence of the color additive by listing its respective common or usual name, "carmine," in the statement of ingredients in accordance with 21 CFR 101.4. However, the label for your "Crab Critters" Appetizer product fails to declare the presence of carmine.

Further, your "Crab Critters" Appetizer product is also adulterated within the meaning of section 402(c) of the Act [21 U.S.C. § 342(c)] because this product bears or contains a color additive which is unsafe within the meaning of section 721 (a) of the Act [21 U.S.C § 379(a)]. Section 721 (a) deems a color additive to be unsafe unless its use is in conformity with the color additive's listing regulation. As noted above, your "Crab Critters" Appetizer product contains the color additive carmine. The listing regulation for carmine requires that the color additive be listed by its common or usual name, "carmine" in the statement of ingredients [21 CFR 73.100(d)(2)]. However, the label for your "Crab Critters" Appetizer product fails to declare the presence of carmine in the statement of
ingredients.

This letter is not intended to be an all-inclusive list of violations. You are responsible for ensuring that your overall operation and the food you distribute comply with the Act and its implementing regulations. You should take prompt action to correct the violations described in this letter and establish and implement procedures which will prevent them from occurring in the future. Failure to take appropriate corrective action may result in enforcement actio without further notice, such as seizure or injunction.

You should notify this office in writing within fifteen (15) working days of receiving this letter of the current status of your corrective actions. Your response should include each corrective action that you have or will take to correct the violations described above, and in particular, what methods and controls you will implement to prevent their recurrence. Please include copies of any documentation that demonstrates the corrections have been implemented. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, please state the reason for the delay and the time frame in which they will be completed.

Your written response should be sent to Lynn S. Bonner, Compliance Officer, at the address noted above. If you have questions concerning this letter, please contact Compliance Officer Bonner at 215-717-3074 or bye-mail at Lynn.Bonner@fda.hhs.gov

Sincerely,

/S/
Kirk D. Soo
District Director
Philadelphia District

Close Out Letter

- Capt'n Chucky's Crab Cake Co., LLC - Close Out Letter 1/6/12[4]

Page Last Updated: 01/13/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

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